GP 1816 #11

PATENT

Attorney Docket No. 014137-008020US
Cytel Ref. 100/80.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Sette et al.

Application No.: 08/452,843

Filed: 5/30/95

For: HLA BINDING PEPTIDES AND THEIR USES

Examiner: T. Cunningham

Art Unit: 1816

TRAVERSAL OF RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants hereby traverse the Restriction Requirement issued in Paper 10 on September 9, 1997, on the grounds that the restriction is in violation of the PTO rules and case law precedent relating to restriction of the claims in an application. Restriction Group I is elected with traversal.

A. The Invention

The present invention comprises supermotifs that allow immunogenic peptides to bind more than one HLA molecule.

B. The Restriction

In paper 10 the Examiner imposed a 20-way restriction requirement on the 3 claims pending in the present application. A copy of the pending claims is attached as Exhibit A. A copy of paper 10 is attached as Exhibit B.

Restriction Groups I-X restrict Claims 1-3 as they encompass or recite an MHC Class I supermotif selected from one of those enumerated below:

I. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Met

II. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Ile

III. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Phe

IV. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Trp

V. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Tyr

VI. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Xaa Met

VII. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Xaa Ile

VIII. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Xaa Phe

IX. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Xaa Trp

X. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Xaa Tyr

Note that Groups I-V are all supermotif-bearing nonapeptides that differ in their carboxyterminal terminal amino acid. Groups VI-X are all supermotif-bearing decapeptides that differ in their carboxyterminal terminal amino acid; the carboxyterminal terminal amino acids are the same as those in groups I-V.

Restriction Groups XI-XX restrict Claims 1-3 as they encompass or recite the exact peptide motifs in Groups I-X, directed to an MHC Class II molecule:

XI. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Met

XII. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Ile

XIII. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Phe

XIV. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Trp

XV. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Tyr

XVI. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Xaa Met

XVII. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Xaa Ile

XVIII. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Xaa Phe

XIX. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Xaa Trp

XX. Xaa Pro Xaa Xaa Xaa Xaa Xaa Xaa Xaa Tyr

In support of the rejection, the Examiner argued that

> Inventions I-XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the classes of peptides comprising different supermotif amino acid sequences have distinct structures, MHC Class I (or Class II) binding properties and/or comprise structurally and functionally distinct T cell epitopes. A search of each distinct peptide motif or structurally distinct peptide places an undue burden upon the Examiner. Further MHC class I binding peptides of different lengths, *i.e.* 9 residues *vs.* 10 residues would be expected to have distinct binding properties due to the constrained size of the MHC Class I binding cleft.

C. Argument: The Restriction Requirement Dividing the Claims Into Twenty Groups was Improper and Should be Withdrawn

As explained in greater detail below, the restriction requirement in the present case does not conform to PTO restriction practice, and is improper. There is no evidence for concluding that the peptides in the different restriction groups (1) have acquired separate classification, (2) have acquired separate status in the art, or (3) require a different field of research. MPEP § 808.02. Furthermore, there is no statutory authority for imposing a restriction requirement on inventions encompassed by a single claim. In fact, the courts have expressly held that the type of restriction requirement made by the Examiner is an improper rejection, and that an Examiner may not use 35 U.S.C. § 121 as a basis for rejection of a particular claim. In addition, imposing a 20-way restriction requirement on the pending

claims would be grossly unfair to Applicants, violating the balance between the administrative interests of the Office and Applicants' constitutional and statutory rights as an inventor.

1. The Restriction Requirement Does Not Conform to PTO Restriction Practice

Restriction of an application is discretionary. A restriction requirement is made to avoid placing an undue examination burden on the Examiner and the Office. Where claims can be examined together without undue burden, the Examiner *must* examine the claims on the merits even though they are directed to independent and distinct inventions. *See,* the MPEP at 803.01. In establishing that an "undue burden" would exist for co-examination of claims, the Examiner *must* show that examination of the claims would involve substantially different prior art searches, making the co-examination burdensome.

MPEP §§ 806.04 and 808.01 ("Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects") were quoted in support of the restriction. These sections relate to restriction of unrelated or independent inventions, defined in MPEP § 806 as having "no disclosed relationship therebetween." However, nothing in the Office Action supports the conclusion that the restricted peptides are incapable of use together or have different modes of operation or different functions or different effects. In addition, "[w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper." MPEP § 806. Although separately patentable, the peptides subject to restriction are related in that they all bear a supermotif and are useful to induce CTL responses. The inventions in the different restriction groups are not distinct as currently claimed, since the claims are directed to peptides that bear the recited supermotifs.

Applicants respectfully submit that the inventions of the proposed restriction groups are related, and that the standards that apply are those discussed in MPEP § 808.02.

To show undue burden resulting from searching difficulties, the Examiner *must* show one of the following:

(1) *Separate classification thereof*:

This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

(2) *A separate status in the art when they are classifiable together*:

Even though they are classified together, each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

(3) *A different field of search*:

Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions.

See, The MPEP at § 808.02, *emphasis added.*

Applying these and related criteria, Applicants respectfully submit that concurrent examination of the pending claims does not create a serious burden on the Examiner. The Examiner has not alleged and there is no evidence that the subject matter of the peptides from the different restricted groups is separately classified, has achieved a separate status in the art, or entails a different field of search. Indeed, the opposite is true: the subject matter of the restricted groups are classified the same, have not achieved a separate status in the art, and/or do not involve a different field of search. In particular, there is no basis for concluding that it is necessary to search for one of the distinct subjects covered by any of the restriction groups in places where no pertinent art to the other restriction groups exists.

2. The Restriction Requirement Contradicts Case Law Precedent

As shown from the restriction outlined above, all of the 20 restricted groups comprise the same claims, *i.e.*, 1-3. On its face, this rejection is flatly improper.

As a preliminary matter, alleging that a particular claim represents multiple "patentably distinct" inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the CCPA has noted:

> As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

See, In Re Weber, Soder and Boksay, 198 USPQ 328, 331 (CCPA 1978) (emphasis added). *See also*, *In Re Haas*, 179 USPQ 623, 624, 625 (*In Re Haas I*) and *In Re Haas*, 198 USPQ 334-337 (*In Re Haas II*).

Moreover, it has long been held that an Examiner may not reject a particular claim on the basis that it represents "independent and distinct" inventions. *See, In Re Weber, Soder and Boksay*, *Supra*. The courts have definitively ruled that the statue authorizing restriction practice, *i.e.*, 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay*, *In Re Haas I* and *In Re Haas II*. In the cases set forth above, the courts expressly ruled that there is no statutory basis for

rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In Re Weber, Soder and Boksay*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334.

Instead of improperly imposing a restriction requirement on a single claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim. *See,* 37 C.F.R. § 1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are complied with. *See,* the MPEP at 803.02. *See also, In Re Wolfrum* 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are incapable of capturing the intended scope of the application. It should be clear that the added costs of filing and prosecuting 20 patent applications in the present case do not strike an appropriate balance between the administrative concerns of the office and Applicants statutory rights as an inventor.

Conclusion: The Restriction Requirement Should be Withdrawn.

For the reasons set forth above, the restriction requirement in the present case should be withdrawn. There is no statutory authority for imposing a restriction requirement on inventions encompassed by a single claim. The courts have expressly held that the type of restriction requirement made by the Examiner is an improper rejection subject to

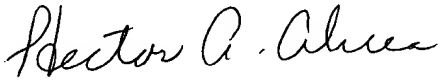
Appellate review. The courts have also expressly held that an Examiner may not use 35 U.S.C. § 121 as a basis for rejection of a particular claim.

In addition, there is no evidence that the subject matter of the restricted groups are classified differently, have achieved a separate status in the art, or involve a different field of search.

Moreover, imposing a 20-way restriction requirement on the pending claims would be grossly unfair to Applicants, violating the balance between the administrative interests of the Office and Applicants' constitutional and statutory rights as an inventor.

Accordingly, Applicants request the withdrawal of the improper 20-way restriction imposed in the present case.

Respectfully submitted,



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Enclosures
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Exhibit B-paper 10

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